Gyrus ACMI CyberWand Transducer and Accessories Storage-Sterilization Trays
Traditional 510(k) Notification
Gyrus ACMI Incorporated
136 Turnpike Road
Southborough, MA 01772

MAY 2 0 2011

510(k) Summary of Safety and Effectiveness
Gyrus ACMI Inc.
Gyrus ACMI CyberWand™ Storage-Sterilization Trays

510k #: K102970

General Information

Manufacturer:	Gyrus ACMI Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Contact Person:	Lorraine Calzetta Regulatory Affairs Tel. #: 508-804-2752 Fax #: 508-804-2624
Date Prepared:	August 26, 2010

Device Description

Classification Name:
Sterilization, wrap, containers and trays
(21CFR 880.6850), Class II

Trade Name:	Gyrus ACMI CyberWand Transducer and Accessories Sterilization Trays
Generic/Common Name:	Sterilization trays

Predicate Devices

Gyros ACMI Flexible Endoscope Storage Sterilization Trays	K092682
Symmetry Medical PolyVac Instrument Delivery System	K040223

Intended Uses

The Gyrus ACMI® CyberWand™ Transducer and Accessories Storage-Sterilization Trays are intended to be used to enclose and protect **only** CyberWand transducers and accessories during steam or EO sterilization. The trays are to be used in conjunction with an FDA cleared sterilization wrap. The trays are optional accessories to the CyberWand transducers and accessories for which they are designed. The trays are indicated for steam or ETO sterilization of **only** the following maximum load per tray: 2 CyberWand Transducers, 2 CyberWand Probe sets. 1 Wrench, 1 Cleaning stylet

EtO Sterilization parameters:
EtO Sterilize using 100% ethylene oxide
Temp: 55 °C, Vacuum 97mmHgV, Preconditioning time 60 minutes, EtO concentration 735-750 mg/L, Exposure time 60 minutes, Humidity 35%-80%, Aeration: 12 hours @55 °C

Product Description

The Gyrus ACMI® Cyber wand Sterilization trays are comprised of plastic lids and bottoms that contain numerous large holes (approximately 7mm in diameter) that permit ready ingress and egress of sterilization gases. The trays are designed to provide protection from physical damage to the transducer and accessories during EtO sterilization and storage. The trays are constructed of biocompatible RADEL-R. The trays do not contact the patient. Radel-R is a polyphenylsulfone plastic that is widely used in medical devices. Radel-R meets the requirements for biocompatibility pursuant to ISO-10993 and is compatible with EtO sterilization.

Performance Data

The maximum load was placed in the tray and inoculated with FDA cleared biological indicator organisms, and chemical indicators were placed. . The trays were wrapped with two layers of FDA approved sterilization wrap and placed into ethylene oxide sterilizer for processing. The system was sterilized successfully by EtO demonstrating 6 log reduction capabilities (SAL of 10^{-6}).

Test systems were exposed to full cycles for EtO. EtO residual testing was performed, with a 12 hour aeration time. Pursuant to ISO10993-7, residual concentrations were within acceptable limits.

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI® CyberWand Transducer and Accessories Storage-Sterilization Tray s are composed of the same materials and utilize similar features as that of the predicates.

The Gyrus ACMI® CyberWand Sterilization trays are comprised of Radel-R plastic lids and bottoms that contain numerous large holes (approximately 7mm in diameter) that permit ready ingress and egress of sterilization gases The trays are constructed of biocompatible RADEL-R. The trays are locked shut with stainless steel clips on each end. The predicate trays have similar design features (numerous large hole that permit ingress and egress of gases.

Like the predicates , the intended use of the trays to provide protection from physical damage to accessories during EtO sterilization and storage. The trays do not contact the patient. Radel-R is a polyphenylsulfone plastic that is widely used in medical devices.. Radel-R meets the requirements for biocompatibility\ pursuant to ISO-10993 and is compatible with EtO sterilization.

The predicates are also composed of Radel R and have the same design philosophy and construction and are compatible with the same sterilization modalities

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 29 2011

Mr. Graham A. L. Baillie
Associate Manager, Regulatory Affairs
Gyrus ACMI, Incorporated
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K102970
Trade/Device Name: ACMI CyberWand™ Transducer and Accessories Storage – Sterilization Trays
Regulation Number: 21CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: October 24, 2011
Received: October 25, 2011

Dear Mr. Baillie:

This letter corrects our substantially equivalent letter of May 20, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

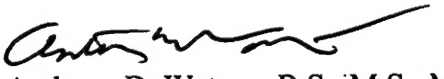
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Gyrus ACMI CyberWand™ Transducer and Accessories Storage - Sterilization Trays

Indications for Use:

The Gyrus ACMI CyberWand™ Sterilization Trays are intended to be used to enclose and protect **only** CyberWand™ transducers and accessories during sterilization. The trays are to be used in conjunction with an FDA cleared sterilization wrap. The trays are optional accessories to the CyberWand™ transducers and accessories for which they are designed.

The trays are indicated for ETO sterilization of **only** the following (maximum load) per tray: 2 CyberWand Transducers, 2 CyberWand Probe sets, 1 Wrench, 1 Cleaning stylet.

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Prescription Use: ____ **OR** Over-the-Counter Use: ___X____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy MD for E. Claverie-Williams
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102970